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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,102	01/25/2001	Roger Craig	10069/1062	5353

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/770,102

Applicant(s)

CRAIG, ROGER

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-76 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, 27, 28, 30, 32-34, 51 and 52 drawn to a method for monitoring activity of one or more enzymes, classified in class 435, subclass 7.1.
- II. Claims 14-27, 29, 31-34, 53 and 54 drawn to a method for monitoring activity of one or more enzymes, classified in class 435, subclass 183.
- III. Claims 35-38, 43-46 and 67-74 drawn to a kit and composition, classified in class 435, subclass 810.
- IV. Claims 39-42, 47-50, 67-74, drawn to a kit and composition, classified in class 435, subclass 975.
- V. Claims 55, 57-66, and 75, drawn to a method for monitoring activity of one or more protease enzymes, classified in class 436, subclass 518.
- VI. Claims 56-66 and 76, drawn to a method for monitoring activity of one or more protease enzymes, classified in class 435, subclass 6.

If Applicants elect Group I or II, the following election of species is required.

This application contains claims directed to the following patentably distinct species of the claimed invention: enzymes in claim 27.

A. kinase

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- B. phosphatase
- C. UDP-N-acetylglucosamine-dolichyl-phosphate-N-acetylglucosamine  
Phosphotransferase
- D. O-GlcNAc transferase
- E. glycylopeptide-N-tetradecanoyl transferase
- F. carbohydrate transferase
- G. ubiquitin activating enzyme E1
- H. a ubiquitin conjugating enzyme E2
- I. ubiquitin conjugating enzyme Ubc9
- J. ubiquitin protein ligase E3
- K. poly (ADP-ribose) polymerase
- L. a fatty acyl transferase
- M. NAD:Arginine ADP ribosyltransferase

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-13 and claims 14-26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together and they have different modes of operation. Invention I promotes binding and detecting binding whereas, Invention II promotes dissociation and detects dissociation.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

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using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as purification of proteins.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention I is a method for monitoring activity of one or more enzymes and Invention I involves promoting binding of binding partner polypeptides and detecting binding whereas, Invention IV involves a kit and composition which promotes dissociation of binding partner polypeptides.

Inventions I and V are different inventions. Invention V involves a method for monitoring activity of one or more protease enzymes and involves immobilized polypeptides which are susceptible to protease digestion whereas Invention I is a method for monitoring the activity of one or more enzymes, Invention I does not involve immobilized polypeptides nor does it involve the immobilized binding partner polypeptides being susceptible to protease digestion. Further, a reference which reads on the recitation of Invention I would not necessarily read on the recitation of Invention V.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions have different modes of operation. Invention I is a method for monitoring activity of one or more enzymes. Invention I promotes bind

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binding and detecting the bind whereas, Invention VI is a method for monitoring activity of one or more protease enzymes. Invention VI promotes dissociation and involves detecting the dissociation.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention II is a method for monitoring activity of one or more enzymes and involves promoting dissociation and detecting dissociation whereas, Invention III involves a composition and kit which promotes binding .

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the purification of proteins.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention to promotes dissociation and involves detecting dissociation whereas, Invention V involves a protease and involves promotion of binding. Invention

V also requires one or more immobilized binding partner polypeptides and Invention II does not require this immobilization.

Inventions II and VI are different inventions. Invention VI involves a method for monitoring activity of one or more protease enzymes and involves immobilized binding partner polypeptides that are susceptible to protease digestion and Invention II does not involve immobilized polypeptides nor does it involve the immobilized binding partner polypeptides being susceptible to protease digestion. Further, a reference which reads on the recitation of Invention II would not necessarily read on the recitation of Invention VI.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are not disclosed as capable of use together have different functions. Invention III a kit and composition which promote binding of binding partner polypeptides whereas the kit and composition of Invention IV promotes dissociation of binding partner polypeptides.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as protein purification.



Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention III involves a composition and kit which promotes binding whereas, Invention VI involves a method which promotes dissociation and detecting dissociation.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention IV involves a composition and kit that promotes dissociation whereas, Invention V involves a method which promotes binding.

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the purification of proteins.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

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the instant case, Invention V involves promoting binding and detecting binding whereas, Invention VI involves promoting dissociation and detecting dissociation.

With respect to inventions A-M, Invention A-M are independent and distinct inventions. They are different enzymes each having unique enzymatic activity, unique structure and operate with unique substrates.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for other restriction for examination purposes as indicated is proper. Furthermore, because the search required for Invention I is not required for Invention V and the search required for Invention II is not required for Invention VI, restriction for examination purposes as indicated is proper. While the searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

#### **Remarks**

It is noted a recited protease in claims 67-74. However, this protease is not claimed. If applicant later claims the recited protease it will be categorized as appropriately.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts  
Examiner  
Art Unit 1641  
June 17, 2002



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP ~~1800~~ 1641